



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0167]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls

Guidance Document: Norovirus Serological Reagents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled “Class II Special Controls Guidance Document: Norovirus Serological Reagents.” This guidance document describes a means by which norovirus serological reagents may comply with the requirement of special controls for class II devices. This guidance document is to be implemented immediately as the special control for norovirus serological reagents.

DATES: Submit either electronic or written comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Class II Special Controls Guidance Document: Norovirus Serological Reagents” to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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10903 New Hampshire Ave,
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Silver Spring, MD 20993-0002,
301-796-6694.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the Federal Register, FDA is publishing a final rule classifying norovirus serological reagents into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for norovirus serological reagents. Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the FD&C Act (21 U.S.C. 360c(f)(1)), request FDA to classify the device under the criteria set forth in section 513(a)(1) of the FD&C Act (21 U.S.C. 360c(a)(1)). FDA will, within 60 days of receiving such a request, classify the device by written order. This classification shall

be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing this classification.

II. Significance of Special Controls Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). Because of the timeframes established by section 513(f)(2) of the FD&C Act, FDA has determined that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is for immediate implementation. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's good guidance practices.

FDA believes that adherence to the recommendations described in this guidance document, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of norovirus serological reagents classified under § 866.3395 (21 CFR 866.3395). In order to be classified as a class II device under § 866.3395, a norovirus serological reagents must comply with the requirements of special controls; manufacturers must address the issues requiring special controls as identified in the guidance document, either by following the recommendations in the guidance document or by some other means that provides equivalent assurances of safety and effectiveness.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive “Class II Special Controls Guidance Document: Norovirus Serological Reagents,” you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1767 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120 and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910-0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 2012.

Nancy K. Stade,
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Center for Devices and Radiological Health.

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